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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In re: Cook Medical, Inc. Pelvic Repair System Products Liability Litigation	**MDL No. 2440**
THIS DOCUMENT RELATES TO:	Case No. 2:13-cv-17315
SHIRLEY BEASLEY and EDWARD BEASLEY, Plaintiffs, vs. COOK BIOTECH, INC., COOK MEDICAL, INC., COOK GROUP, INC., DIMA S.L., NEOMEDIC INTERNATIONAL, S.L., NEOMEDIC, INC. and SPECIALTIES REMEEX INTERNATIONAL S.L., Defendants.	Jury Trial Demanded

ORIGINAL COMPLAINT

COME NOW Plaintiffs SHIRLEY BEASLEY and EDWARD BEASLEY, and for their causes of action against Defendants Cook Biotech, Inc., Cook Medical, Inc., Cook Group, Inc.,

DIMA S.L., Neomedical International, S.L., Neomedic, Inc., and Specialties Remeex International, S.L., as follows:

GENERAL ALLEGATIONS
PARTIES AND SERVICE

1. Plaintiffs SHIRLEY BEASLEY and EDWARD BEASLEY are residents of Peach County, Georgia.

2. Defendant Cook Biotech, Inc. is an Indiana corporation with its corporate headquarters in Indiana. Defendant may be served through its registered agent, Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, Indiana 46204.

3. Defendant Cook Medical, Inc. is an Indiana corporation with its corporate headquarters in Indiana. Defendant may be served through its registered agent, Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, Indiana 46204.

4. Defendant Cook Group, Inc. is an Indiana corporation with its corporate headquarters in Indiana. Defendant may be served through its registered agent, Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, Indiana 46204.

5. Defendant DIMA, S.L. ("DIMA") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at Poligono Industrial Mediavega Parcela 2.9, Calatayud, Zaragoza, Kingdom of Spain 50300. DIMA's registered United States Food and Drug Administration ("FDA") Agent is Jeffrey R. Shideman, residing at 7307 Gouchester Dr., Edina, Minnesota 55435.

6. Defendant Neomedic International, S.L. ("Neomedic International") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at C/Maestrat, 41-43 Terrassa, Barcelona, Spain 08225.

7. Defendant Neomedic Inc. ("Neomedic") is a corporation organized and existing under the laws of Florida, with its principal place of business at 2655 Le Jeune Road, #810, Coral Gables, Florida, 33134. Defendant Neomedic Inc. is the United States headquarters of Neomedic International, S.L.

8. Defendant Specialties Remeex International, S.L. ("SRI") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at C/Tren De Baix, 55 Baixos Terrassa, Barcelona, Kingdom of Spain 08223. SRI's registered United States Food and Drug Administration ("FDA") Agent is Jeffrey R. Shideman, residing at 7307 Gouchester Dr., Edina, Minnesota 55435. Defendant SRI is registered with the FDA as the owner/operator of Neomedic International.

9. Cook Biotech, Inc., Cook Medical, Inc., Cook Group, Inc., DIMA S.L., Neomedic International, S.L., Neomedic, Inc. and Specialties Remeex International S.L. are collectively referred to as "DEFENDANTS" throughout this complaint.

10. This is a lawsuit for personal injury damages in excess seventy-five thousand dollars ($75,000) exclusive of interest and costs. The parties are citizens of different states. Subject matter jurisdiction is proper in this Court pursuant to the provisions of 28 U.S.C. § 1332.

11. Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the Southern District of West Virginia because it placed a defective product in the stream of commerce and that product caused personal injuries to Plaintiff Shirley Beasley in her State of Georgia.

FACTUAL ALLEGATIONS

12. On or about November 10, 2011, Plaintiff underwent surgery to treat stress urinary incontinence and pelvic organ prolapse. The medical device used during surgery was the Cook Surgis Biodesign and the DIMA Remexx System ("Products").

13. Plaintiff was implanted with Products studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, and/or sold or otherwise placed in the stream of interstate commerce of the United States, including this state, by Defendants.

14. Defendant DIMA's FDA registration lists its proprietary device as "Needleless Sling." Defendant Neomedic International is registered with the FDA as a foreign exporter and specification developer of the "Needless Sling."

15. Defendant Specialties Remeex International, S.L. submitted the 510(k) summary to the FDA for the Remeex System for treatment of female stress urinary incontinence.

16. At all times material hereto, the Cook Medical Surgis and Remeex System and any other of Defendants' polypropylene or polymeric pelvic mesh products were designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold in the stream of commerce by Defendants, for implantation into individuals, including Plaintiff.

17. At all times herein mentioned the officers and directors of Defendants participated in, authorized and directed the production and promotion of the Products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the Products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiffs.

18. The Products were promoted by Defendants as safe and effective treatment for female urinary incontinence that could be installed by urologists in their patients quickly and on an outpatient basis. Plaintiffs and/or their physicians relied on Defendants' promises of safety. What Plaintiffs received, however, were not safe devices, but devices known by Defendants to cause serious internal injuries.

19. After, and as a result of the implantation of the Products, Plaintiffs have suffered and will continue in the future to suffer severe and permanent bodily injuries and significant mental and physical pain and suffering, economic losses, and impairment of personal relations.

20. Defendants developed technology to treat conditions related to the pelvic health of women, specifically stress urinary incontinence ("SUI"). The synthetic mesh systems are purported to remedy SUI by implantation of polypropylene or polymeric mesh transvaginally inside the pelvic region of a woman's body.

21. Defendants' "SUI" products are targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakening or damage to the urethra. These products are specifically promoted to physicians and patients as innovative, involving minimally invasive procedures with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting pelvic organ prolapse and stress urinary incontinence.

22. Prior to the implantation of the Products at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") clearance (not approval) to market their pelvic or transvaginal mesh products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed "substantially equivalent" to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

23. Despite claims that the polypropylene mesh in pelvic mesh products is inert, the scientific evidence and literature show that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers and physicians should have been aware of this literature.

24. Defendants marketed and sold their pelvic mesh products through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of these products.

25. Contrary to the representations and marketing of Defendants, their pelvic mesh products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiffs. The defects stem from many issues, including: the use of polypropylene material in the pelvic mesh products and the immune reaction that results;

a. the design of the pelvic mesh products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

b. the contraction or shrinkage of the mesh;

c. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade;

d. the use and design of anchors in some of the pelvic mesh products that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

e. degradation of the mesh itself over time which causes the internal tissue to degrade;

f. degradation of the mesh over time which creates or causes the release of carcinogenic substances;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue;

h. the design of the trocars (devices used to insert the pelvic mesh products into the vagina and into the pelvic region) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings; and

i. the use of component material not intended for implantation into the human body, especially long term.

26. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of its pelvic mesh products to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public, including Plaintiffs and their treating physicians.

27. Despite the chronic underreporting of adverse events associated with the pelvic mesh products, enough complaints were recorded for the Food and Drug Administration to issue a public health notification regarding the dangers of these devices.

28. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the pelvic mesh products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants are among the manufacturers of the products that are the subject of the notification.

29. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or

quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

30. Defendants further knew or should have known the following:

a. that some of the predicate devices for the pelvic mesh products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the pelvic mesh products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the pelvic mesh products were and are causing numerous patients severe injuries and complications.

31. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the pelvic mesh products.

32. Defendants failed to design and establish a safe, effective procedure for removal of the pelvic mesh products; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the pelvic mesh products.

33. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter.

34. Defendants' pelvic mesh products were at all times utilized and implanted in a manner foreseeable to Defendants as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained implanting physicians.

35. Defendants provided incomplete and insufficient training and information to physicians to increase the number of physicians utilizing its pelvic mesh products, and thus increase the sales of these products.

36. The pelvic mesh products implanted into Plaintiffs were in the same or substantially similar condition as it was when each left the possession of Defendants, as well as being used in the condition directed by and expected by Defendants.

37. The injuries, conditions, and complications suffered by women who have been implanted with pelvic mesh products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

38. At all relevant times herein, Defendants continued to promote pelvic mesh products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

39. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiffs, their physicians, and the public on notice of the dangers and adverse effects caused by implantation of the pelvic mesh products.

40. The pelvic mesh products were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

CAUSES OF ACTION

FIRST CAUSE OF ACTION: NEGLIGENCE

41. Plaintiffs incorporate by reference the forgoing paragraphs as if fully set forth herein.

42. On the occasion in question, the injuries and damages sustained by each Plaintiff was proximately caused by the negligence of Defendants, in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and/or selling the pelvic mesh products.

43. Each act or omission of negligence was a proximate cause of the damages and injuries to each Plaintiff.

SECOND CAUSE OF ACTION: STRICT LIABILITY-DESIGN DEFECT

44. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

45. At the time each implanting surgeon implanted Defendants' pelvic mesh products in each Plaintiff, Defendants were engaged in the business of selling these products.

46. The pelvic mesh products were defectively designed when sold.

47. The pelvic mesh products were unreasonably dangerous, taking into consideration the utility of these products and the risks involved in their use.

48. The pelvic mesh products reached each Plaintiffs' implanting surgeon and Plaintiff without substantial change in the condition in which they were sold.

49. The defective and unreasonably dangerous condition of the pelvic mesh products was the proximate cause of the damages and injuries to each Plaintiff.

50. Thus, Defendants are strictly liable to Plaintiffs.

THIRD CAUSE OF ACTION:
STRICT LIABILITY- MANUFACTURING DEFECT

51. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

52. At the time each Plaintiff's doctor implanted the pelvic mesh products in each Plaintiff, Defendants were engaged in the business of selling these products.

53. The pelvic mesh products were defectively designed when sold.

54. The pelvic mesh products were unreasonably dangerous, taking into consideration the utility of these products and the risks involved in their use.

55. The pelvic mesh products reached implanting surgeons and Plaintiffs without substantial change in the condition in which they were sold.

56. The defective and unreasonably dangerous condition of the pelvic mesh products was a proximate cause of the damages and injuries to Plaintiffs.

57. Thus, Defendants are strictly liable to Plaintiffs.

FOURTH CAUSE OF ACTION:
STRICT LIABILITY- FAILURE TO WARN

58. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

59. The pelvic mesh product(s) implanted in each Plaintiff was not reasonably safe for intended use and was defective as a matter of law due to their lack of appropriate and necessary warnings.

60. As a direct and proximate result of the pelvic mesh products' aforementioned defects, Plaintiffs were caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

61. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

FIFTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

62. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

63. Defendants made assurances to the general public, hospitals, and health care professionals that the pelvic mesh products were safe and reasonably fit for their intended purpose.

64. Plaintiffs and/or their healthcare providers chose the pelvic mesh products based upon Defendants' warranties and representations regarding the safety and fitness of the pelvic mesh product.

65. Plaintiffs, individually and/or by and through their physicians, reasonably relied upon Defendants' express warranties and guarantees that the pelvic mesh products were safe, merchantable, and reasonably fit for their intended purpose.

66. Defendants breached these express warranties because the pelvic mesh products implanted in Plaintiffs were unreasonably dangerous and defective and not as Defendant had represented.

67. Defendants' breaches of express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiffs' bodies, placing Plaintiffs' health and safety in jeopardy.

68. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiffs were caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages for which Defendants are liable.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

69. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

70. Defendants impliedly warranted that the pelvic mesh products were merchantable and were fit for the ordinary purpose for which they were intended.

71. When the pelvic mesh product(s) was/were implanted in each Plaintiff to treat her medical conditions, the product(s) was/were being used for the ordinary purpose for which intended.

72. Plaintiffs, individually and/or by and through their physicians, relied upon Defendants' implied warranty of merchantability in consenting to have the pelvic mesh products implanted in them.

73. Defendants breached this implied warranty of merchantability because the pelvic mesh product(s) implanted in each Plaintiff was/were neither merchantable nor suited for their intended use as warranted.

74. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiffs' bodies, placing Plaintiffs' health and safety in jeopardy.

75. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiffs were caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages for which Defendants are now liable.

PUNITIVE DAMAGES

76. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

77. Defendants conduct in designing, manufacturing, marketing, labeling, packaging and selling the unreasonably safe and defective pelvic mesh products amounted to outrageous, unconscionable willful, wanton, and/or reckless conduct and/or criminal indifference to civil obligations affecting the rights of others, including Plaintiffs.

78. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious and were done with a conscious disregard for the rights of

Plaintiffs and other users of Defendants' products and for the primary purpose of increasing Defendants' profits from the sale, distribution, and use of Defendants' products. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against each Defendant in an amount appropriate to punish and make an example of each Defendant.

79. Plaintiffs are therefore entitled to an award of punitive damages.

VICARIOUS LIABILITY

80. Whenever in this Complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, or representatives.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

81. Plaintiffs incorporate by reference the factual portion of this Complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

82. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

83. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages and their relationship to the pelvic mesh products were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate

application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

84. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injuries and the connection between the injuries and Defendants' tortious conduct.

DEMAND FOR JURY TRIAL

85. Plaintiffs hereby request a jury trial.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against Defendants COOK BIOTECH, INC., COOK MEDICAL, INC., COOK GROUP, INC., DIMA S.L., NEOMEDIC INTERNATIONAL, S.L., NEOMEDIC, INC. and SPECIALTIES REMEEX INTERNATIONAL S.L., for past and future general damages in an amount in excess of the $75,000;

1. for general damages for personal injury, including permanent impairment, physical injury, physical and mental pain and suffering, distress, loss of enjoyment of life, and loss of consortium;
2. for past and future medical and incidental expenses, according to proof;
3. for past and future loss of earnings and/or earning capacity, according to proof;
4. for prejudgment interest on all damages as is allowed by law;
5. for past and future costs of suit incurred herein;
6. for punitive and exemplary damages in an amount to be determined at trial; and
7. for such other and further relief as the Court deems just and proper.

Dated: 4 July 2013

Respectfully Submitted,

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